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(54) Outer Shell of Soft Capsule

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Specification

1. Title of the Invention

Outer Shell of Soft Capsule

2. Scope of Patent Claim

The outer shell of a soft capsule, the starting material of which is a natural polysaccharide-polyhydric alcohol composition obtained by uniformly mixing at least one natural polysaccharide of the following: carrageenan, alginic acid, alginic acid derivative, agar, locust bean gum, guar gum, tamarind seed polysaccharide, pectin, xanthan gum, glucomannan, chitin, pullulan, and cyclodextrin in a concentrated solution of at least one of the following: polyhydric alcohol, sugar alcohol, monosaccharide, disaccharide, and oligosaccharide in the presence or absence of an alkali.

3. Detailed Description of the Invention

[Industrial Field of Use]

The present invention pertains to the outer shell of a soft capsule that can be filled with a substance other than an oil.

[Prior Art]

Soft capsules are capsules wherein an oleaginous drug, etc., is introduced into a sheet made mainly of gelatin. These capsules have advantages in that the amount of liquid they hold is exact, their adhesive surface is perfectly sealed and therefore, there is no leakage and the contents are protected from outside air, in

turn making it possible to prevent oxidation and improve shelf life, and the productivity is high, etc.

Conventional soft capsules are made by mixing a gelatin starting material with glycerin or sorbitol, etc., to make an aqueous solution, gelling this solution and making the gel into a sheet, feeding two such sheets from a left and a right pair of die rolls while heating, continuously introducing and sealing the liquid between the two sheets, and drying.

[Problems to be Solved by the Invention]

As previously mentioned, soft capsules are excellent in terms of shelf life of their contents, their high productivity, etc., but because the gelatin is dissolved in water, their contents cannot be in the form of an aqueous solution and the only drug that can be introduced inside these capsules is one that can be dissolved in an oleaginous solvent. This restricts the use of soft capsules. Therefore, there is a need for an outer shell in soft capsule form that can even be filled with an aqueous solution.

[Means for Solving Problems]

The present invention solves the above-mentioned problems, its structure being characterized in that it uses as the starting material of the outer shell of the soft capsule a natural polysaccharide-polyhydric alcohol composition obtained by uniformly mixing at least one natural polysaccharide selected from carrageenan, alginic acid, alginic acid derivative, agar, locust bean gum, guar gum, tamarind seed polysaccharide, pectin, xanthan gum, glucomannan, chitin, pullulan, and cyclodextrin in a concentrated solution of at least one of the following: polyhydric

alcohol, sugar alcohol, monosaccharide, disaccharide, and oligosaccharide in the presence or absence of an alkali.

Polyhydric alcohols in the narrow sense of the word, such as propylene glycol, glycerin, etc., are given as polyhydric alcohols pertaining to the present invention. Sorbitol, mannitol, maltitol, xylitol, reduced starch saccharification product, etc., are given as sugar alcohols. Glucose, fructose, galactose, xylose, etc., are used as monosaccharides. Saccharose, maltose, lactose, etc., are used as disaccharides. The products of decomposition of starches such as sweet potato, white potato, and corn by enzymes, acids, etc., are used as oligosaccharides, and include disaccharides, trisaccharides, tetrasaccharides, pentasaccharides, hexasaccharides, etc.

Carrageenan, alginic acid, alginic acid derivative, agar, locust bean gum, guar gum, tamarind seed polysaccharide, pectin, xanthan gum, glucomannan, chitin, which is a type of mucopolysaccharide, pullulan, cyclodextrin, etc., can be widely used as natural polysaccharides.

Depending on the case, an alkali is preferably used concomitantly. The alkali should be an ordinary inorganic or organic alkaline substance, such as sodium hydroxide, potassium hydroxide, calcium hydroxide, magnesium hydroxide, barium hydroxide, sodium carbonate, potassium carbonate, calcium carbonate, ammonium carbonate, magnesium carbonate, sodium bicarbonate, ammonium bicarbonate, basic amino acid, amine, etc. When an alkali is added, strength and heat resistance will usually improve.

Furthermore, proteins can also be used concomitantly with the above-mentioned natural polysaccharides. Soy proteins, wheat protein, milk proteins, egg white, collagen, collagen decomposition products, microorganism proteins, etc., are given as the protein. Polypeptide, dipeptide, tripeptide, and amino acids are given as protein decomposition products. There is usually a tendency toward an increase in strength with a composition that is obtained by concomitant use of protein to replace part of the natural polysaccharide.

The present invention is characterized in that the natural polysaccharide is reacted in a concentrated solution of at least one of these polyhydric alcohols, sugar alcohols, monosaccharides, disaccharides and oligosaccharides. The concentrated solution is either the liquid form itself, or a slightly diluted liquid. The powder is made into an aqueous 30 to 90%, preferably 50 to 80%, more preferably 60 to 80%, solution and at least one of the above-mentioned polysaccharides is kneaded in this solution.

The temperature at which kneading is performed is 5 to 150°C, preferably 10 to 100°, more preferably 20 to 80°C. Even if kneading is performed at a low temperature, the reaction will be sufficient as long as the product is then heated when it is later dried, etc. In general, a composition with a delicate structure is obtained at a high temperature, while a composition whose mesh-like structure is coarse and brittle is obtained at a low temperature.

The mixture ratio of natural polysaccharide and at least one compound selected from: polyhydric alcohol, sugar alcohol, monosaccharide, disaccharide,

and oligosaccharide is 0.05 to 15 parts by weight, preferably 0.1 to 10 parts by weight, of these compounds to 1 part by weight of natural polysaccharide.

The composition obtained by kneading the above-mentioned starting materials is usually a slightly damp powder. When this is dissolved in water, it forms a sticky solution or paste with a solids content of 2 to 10% and can irreversibly congeal by being set aside at normal temperature, frozen, refrigerated or heated. Moreover, the congealed product that is obtained is preferred as the outer shell of a soft capsule because its properties, particularly strength, heat resistance and dissolution temperature in water, can be adjusted as needed by adjusting the starting materials that are used.

The following are given as embodiments of the outer shell of a soft capsule of the present invention:

(A) A substitute for a gelatin sheet that has been made by molding an aqueous solution of the composition pertaining to the present invention into a sheet with a thickness of 5 to 500 μ, preferably 10 to 50 μ,

(B) A sheet that has been obtained by layering a gelatin sheet and a sheet of the composition pertaining to the present invention so that the sheet pertaining to the present invention is on the inside,

(C) A sheet that has been obtained by mixing a gelatin solution for soft capsules and a solution of the composition pertaining to the present invention.

Aqueous vitamin solutions of vitamin B_1, B_2, B_5, B_6, B_{12}, niacin, folic acid, vitamin C, etc., nutrients, such as saccharides, proteins, minerals, etc., encapsulated flavorings and seasonings, toiletries that are used in small amounts

at a time, etc., which have been difficult to use as a conventional oleaginous solution, are given as substances that are introduced into the soft capsule.

[Effects]

Natural polysaccharides have a complex structure with various reactive groups and side chains and therefore, apparently react in concentrated solutions in which many hydroxyl groups are present at high concentrations to form a complex matrix. When water is added to this, an even more complex three-dimensional structure is produced and a water-resistant, heat-resistant congealed product is irreversibly formed to produce a unique gel.

This type of gel is water-resistant and therefore, it can be preferably used as the outer shell of a soft capsule in which a substance such as a drug, a food product, or toiletry in the form of an aqueous solution is sealed and stored.

[Example 1]

One-hundred parts of gelatin, 30 parts of glycerin, and 60 parts of water were agitated and dissolved at 75°C and defoamed with a vacuum pump. A gelatin film with a thickness of 450 μm was obtained with a rotary-type continuous soft-capsule automatic filling device.

Five parts by weight of glucomannan, 2 parts by weight of carrageenan, and 1 part by weight of xanthan gum were separately kneaded with 1.5 parts of an 80% sucrose solution for 10 minutes at 80°C. Three parts by weight of the composition that was obtained were dissolved in 97 parts by weight of water and this aqueous solution was made into film by the wet casting method to obtain a film with a thickness of 25 μ. Two sets of double film in which the above-

mentioned gelatin film was layered onto this film were made. The two sets of films, a right and a left set, were passed through a pair of die rolls and heated and pressed while an aqueous L-ascorbic acid solution (concentration of 30%) was introduced under pressure by a filling pump to form capsules of 500 mg ascorbic acid/capsule.

[Example 2]

Glucomannan	5 parts
Carrageenan	0.5 part
Calcium carbonate	0.12 part
Glycerin	1 part

The above-mentioned components were kneaded for 30 minutes at 70°C and then 3 parts of the composition that was obtained were dissolved in 97 parts of water. The sticky aqueous solution that was obtained was made into film by the wet casting method to obtain a film with a thickness of 15 μ. The outer shell of a soft capsule having a two layered structure was obtained as in Example 1 using this film and a gelatin film. Soft capsules in which 2 g/capsule of flavoring liquid for instant chicken soup were introduced were obtained. When 150 ml of hot water at 90°C were added to one of these soft capsules and thoroughly agitated, the soft capsule broke to make chicken soup.

[Example 3]

One-hundred parts of gelatin, 30 parts of glycerin, and 10 parts of water were agitated and dissolved at 75°C. This was defoamed with a vacuum pump to obtain solution A. Five parts of glucomannan, 3.5 parts of carrageenan, and

1.5 parts of glycerin were separately kneaded at 70°C and 3 parts of the composition of the present invention that was obtained were dissolved in 97 parts of water to obtain aqueous solution B. Sixty parts of A and 40 parts of B were thoroughly kneaded and 290 mg of astringent lotion/capsule were introduced into No. 5 soft capsules by the conventional rotary die method using a rotary-type soft-capsule continuous automatic filling device. At the time of use, the soft capsule was pierced with a pin to obtain a dose of astringent lotion.

[Results]

By means of the present invention, it is possible to encapsulate hydrophilic contents in the form of an aqueous solution in a soft capsule, further increasing the use of soft capsules.

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Linda Hutchinson